2-11-02

510(k) Summary of Safety and Effectiveness

K020052

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis SMART™ Nitinol Stent Transhepatic Biliary System – 40 cm	Biliary Stent

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis SMART™ Nitinol Stent Transhepatic Biliary System (510(k) # K001843 – July 18, 2000).

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The **Cordis SMART™ Nitinol Stent Transhepatic Biliary System – 40 cm** is intended for use in the palliation of malignant neoplasms in the biliary tree.

Device Description

The device description of the proposed **Cordis SMART™ Nitinol Stent Transhepatic Biliary System – 40 cm** is as follows.

- 7 French stent delivery system profile;
- Stent material – Nickel Titanium alloy and tantalum micromarkers;
- Expanded stent diameters 6, 7, 8, 9, and10 mm;
- Stent lengths: 20, 40, 60, and 80 mm;
- Stent delivery system usable length 40 cm; and
- Guidewire lumen 0.035".

Biocompatibility

All materials used in the **Cordis SMART™ Nitinol Stent Transhepatic Biliary System – 40 cm** are biocompatible.

Summary of Substantial Equivalence

The **Cordis SMART™ Nitinol Stent Transhepatic Biliary System – 40 cm** is substantially equivalent to the predicate device. The equivalence was confirmed through pre-clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Mr. Sam Mirza
Manager, Regulatory Affairs
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K020052
Trade/Device Name: Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System – 40 cm
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: January 4, 2002
Received: January 8, 2002

Dear Mr. Mirza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Bernard L. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020052

Device Name: Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System – 40 cm

FDA's Statement of the Indications For Use for device:

The Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System – 40 cm is intended for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use √ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number [redacted]